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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,728	10/25/2001	Roberto Fagnani	71726 / 6776	3521

7590 06/23/2005

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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,728	Applicant(s) FAGNANI ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, drawn to a biochip, classified in class 435, subclass 287.2.
 - II. Claim 18, drawn to a hydrogel biochip, classified in class 435, subclass 287.7.
 - III. Claims 19 and 20, drawn to a method of using a biochip, classified in class 436, subclass 528.
 - IV. Claims 21, 22, and 23 (*This claim is improperly dependent on a product claim 10 and in order to further prosecution it is interpret to depend on claim 21. Appropriate correction is required*), drawn to a method of preparing an optically clear isocyanate-functional hydrogel chip, classified in class 436, subclass 533.
 - V. Claims 24-28, drawn to a method of preparing an isocyanate-functional hydrogel chip having immobilized proteins, classified in class 435, subclass 7.1.
 - VI. Claims 29 and 30, drawn to a method of preparing an isocyanate-functional hydrogel chip having a plurality of cells, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and Group II are drawn to two distinct products, which differ in their structural features. Group I is drawn to a biochip with a binding entity immobilized within or upon said hydrogel cell. Group II is drawn to a hydrogel biochip with different protein binding entities bound to the intermediate agents. Thus, these products of Groups I, and II have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01) and thus the restriction between these groups is proper.

3. Inventions of Group III, Group IV, Group V, and Group VI are drawn to four distinct methods, which differ in their method steps. The different method steps have different functions and modes of operation. Group III requires the method step of contacting the hydrogel biochip with an analyte solution, containing a target biomolecule under binding conditions. Group IV requires the method step of covalently binding said entity to the isocyanate-functional hydrogel prepolymer via reaction with not more than 15% of said reactive isocyanates. Group V requires the method step of exposing individual hydrogel droplets to one of said desired protein solutions to immobilize the protein capture agents. Group VI requires the method step of dispensing droplets of the polymerizing isocyanate-functional hydrogel prepolymer onto a solid substrate so that the droplets become attached to the substrate and form a plurality of cells. Thus, these four different inventions as claimed have different method steps that have different functions and modes of operation (MPEP § 806.04, MPEP § 808.01) and thus the restriction between these groups is proper.

4. Inventions of Group I (product) and Group III (process) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as screening for pharmaceutically effective compounds. This restriction requirement is also applicable with the product of Group II.

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5. Inventions of Group I (product) and Group IV (process) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown:

(1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP §

806.05(f)). In the instant case the product as claimed can be made by another and materially

different process such as the processes of either Group V or VI or the process of

electropolymerization. This restriction requirement is also applicable with the product of Group

II.

6. Inventions of Group I (product) and Group V (process) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown:

(1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP §

806.05(f)). In the instant case the product as claimed can be made by another and materially

different process such as the processes of either Group IV or VI or the process of

electropolymerization. This restriction requirement is also applicable with the product of Group

II.

7. Inventions of Group I (product) and Group VI (process) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown:

(1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP §

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806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as the processes of either Group IV or V or the process of electropolymerization. This restriction requirement is also applicable with the product of Group II.

8. Because these inventions are distinct for the reasons given above and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group II would involve a determination of the patentability of the hydrogel biochip while a patentability determination for Group V would involve a consideration of the patentability of the method of preparing an isocyanate-functional hydrogel chip having immobilized proteins. These considerations are very different in nature.

Even though some of the groups are classified in the same class and/or subclass, this has no effect on the non-patent literature search. Different groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

10. *If applicants elect the invention of Group I*, applicants are required to elect *one single* species from *each* of the following a)-b) that result in a *single specific* species of biochip:

- a) A *single specific* species of hydrogel cell.
- b) A *single specific* species of binding entity.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected a single specific species of composition, wherein each specific substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

The species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

11. *If applicants elect the invention of Group II, applicants are required to elect **one single** species from **each** of the following a)-c) that result in a **single specific** species of hydrogel biochip:*

- a) A *single specific* species of hydrogel cell.
- b) A *single specific* species of intermediate agent.
- c) A *single specific* species of binding entity.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected a single specific species of composition, wherein each specific substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

The species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon, including any claims subsequently added.*** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct

June 17, 2005


PADMAASHRI PONNALURI
PRIMARY EXAMINER